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BRINKS HOFER GILSON & LIONE			MALLARI, PATRICIA C	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	10/510,164	HARPAS ET AL.
	<b>Examiner</b>	<b>Art Unit</b>
	Patricia C. Mallari	3735

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 05 September 2007.  
 2a) This action is FINAL.                    2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-31 is/are pending in the application.  
 4a) Of the above claim(s) 29-31 is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 1-6,8 and 11-28 is/are rejected.  
 7) Claim(s) 7,9, 10 is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on 01 October 2004 is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>10/1/04</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application |
|  | 6) <input type="checkbox"/> Other: _____                          |

**DETAILED ACTION**

***Election/Restrictions***

Applicant's election without traverse of Group II in the reply filed on 9/5/07 is acknowledged. Claims 29-31 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected Group II, there being no allowable generic or linking claim.

***Information Disclosure Statement***

The information disclosure statement (IDS) submitted on 10/1/04 was considered by the examiner. The first two references listed under the section "US Patent Documents" are not US patent documents. Those references have been crossed out and their information inserted in the section "Foreign Patent Documents".

***Drawings***

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the following must be shown or the features canceled from the claims: the skin depressing means distal surface protruding from the pressure sensing head distal end in the application direction, as claimed in claim 3; the handle wherein the distance between the skin depressing means distal surface and the handle varies relative to the application pressure applied to the user's skin and the distance between the pressure sensing head distal end and the handle is fixed, as claimed in claims 7 and 9, a compression spring

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arrangement between the pressure sensing head and the handle, as claimed in claim 10, and the skin depressing means having a substantially annular distal surface, as claimed 12. No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

### ***Claim Objections***

Claims 13, 14, 16, 17, and 27 are objected to because of the following informalities:

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On line 2 of claim 13, "wherein the device has a" should be replaced with  
"wherein the at least one skin depressing means comprises a".

On line 2 of claim 14, "wherein the device has a pair" should be replaced with  
"wherein the at least one skin depressing means comprises a pair of".

On line 3 of claim 14, "either" should be replaced with "on either".

On line 2 of claim 16, "surface(s)" should be replaced with "surfaces".

On line 3 of claim 17, "around the" should be replaced with "around the artery".

On line 7 of claim 17, "differs than" should be replaced with "differs from".

On line 3 of claim 27, "being either" should be replaced with "being on".

Appropriate correction is required.

### ***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 13, 14, and 16 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claim 13 recites, "a single skin depressing means positioned, in use, on one side of the artery". Claim 14 recites, "a pair skin depressing means positioned, in use, either side of the artery" (sic). Claim 16 recites, "the skin depressing means distal surface(s) are each oriented substantially normally to the longitudinal direction of the artery". The human body or part thereof (artery) is non-statutory subject matter and cannot positively be claimed. The applicants

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may overcome this rejection, for example, by replacing "positioned" with "adapted to be positioned".

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Or

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 3, 4, 11, 13, 14, and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent No. 3,704,708 to Iberall. Iberall teaches a device for transcutaneous pressure waveform sensing of an artery, the device having, in use, an application direction towards the skin of the user in the direction of an underlying artery. The device includes a pressure sensing head 28 having a distal end and at least one skin depressing means, 20, 22, substantially adjacent the pressure sensing head and having a distal surface. The pressure sensing head distal end and skin depressing means distal surface are sized such that the pressure sensing head distal end is spaced apart, in the application direction, from the skin depressing means distal surface (see entire document, especially figs. 2 and 3; col. 3, lines 15-60 of Iberall).

Regarding claim 3, the skin depressing means distal surface 20, 22 protrudes from the pressure sensing head distal end in the application direction (see entire document, especially figs. 2 and 3 of Iberall).

Regarding claim 4, the distance between the skin depressing means distal surface and the pressure sensing head distal end is fixed (see entire document, especially figs. 2 and 3; col. 3, lines 21-60 of Iberall).

Regarding claim 11, the device has a single skin depressing means 20 (see entire document, especially figs. 2 and 3 of Iberall).

Regarding claim 13, the skin depressing means is positioned in use, on one side of the artery (see entire document, especially fig. 3 of Iberall).

Regarding claim 14, the device has a pair of skin depressing means 20, 22 positioned, in use, on either side of the artery (see entire document, especially fig. 3 of Iberall).

With further regard to claim 16, the skin depressing means distal surfaces are each oriented substantially normally to the longitudinal direction of the artery (see entire document especially fig. 3 of Iberall).

Claims 1, 2, 4, 5, and 11-13 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent No. 4,987,900 to Eckerle et al. Eckerle teaches a device for transcutaneous pressure waveform sensing of an artery, the device having, in use, an application direction towards the skin of a user in the direction of an underlying artery. The device comprises a pressure sensing head 40 having a distal end and at least one

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skin depressing means 42, 44 substantially adjacent the pressure sensing head and having a distal surface. The skin depressing means 42, 44 is capable of depressing the skin. The pressure sensing head distal end and skin depressing means distal surface are sized such that the pressure sensing head distal end is spaced apart, in the application direction, from the skin depressing means distal surface (see entire document, especially figs. 4 and 5; col.4, lines 67-col. 5, line 44 of Eckerle).

Regarding claim 2, the pressure sensing head distal end protrudes from the skin depressing means distal surface in the application direction (see entire document, especially figs. 4 and 5 of Eckerle).

Regarding claims 4 and 5, the distance between the skin depressing means and the pressure sensing head distal end is fixed (see entire document, especially figs. 4 and 5 of Eckerle).

Regarding claim 5, the distance between the skin depressing means distal surface and the pressure sensing head distal end is approximately 2 mm (see entire document, especially claim 3 of Eckerle).

Regarding claim 11, the device has a single skin depressing means (see entire document, especially figs. 4 and 5 of Eckerle).

Regarding claim 12, the skin depressing means has a substantially annular distal surface (see entire document, especially figs. 4, 5; col. 4, lines 36-44 of Eckerle).

Regarding claim 13, the device has a single skin depressing means positioned, in use, on one side of the artery (see entire document, especially fig. 4 of Eckerle).

Claims 1, 4, 6, 11, 13, 14, 16-18, 22, 25, 26, and 28 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent No. 6,432,060 to Amano. Amano teaches a device for transcutaneous pressure waveform sensing of an artery, the device having, in use, an application direction towards the skin of a user in the direction of an underlying artery, wherein the device of Amano can be oriented in any manner during use. The device includes a pressure sensing head 22 having a distal end and at least one skin depressing means 14 substantially adjacent the pressure sensing head and having a distal surface (see entire document, especially fig. 3; col. 9, line 42-col. 10, line 12 of Amano). The pressure sensing head distal end and skin depressing means distal surface are sized such that the pressure sensing head distal end is spaced apart in the application direction from the skin depressing means distal surface (see entire document, especially fig. 3 of Amano).

Regarding claim 4, the distance between the skin depressing means distal surface and the pressure sensing head distal end is fixed (see entire document, especially fig. 3 of Amano), wherein the distance is at least fixed during measurement.

Regarding claim 6, the distance between the skin depressing means 78 distal surface and the pressure sensing head 22 distal end is variable (see entire document, especially fig. 14; col. 17, lines 15-32 of Amano).

Regarding claim 11, the device has a single skin depressing means (see entire document, especially fig. 3; col. 9, line 63-col. 10, line 5 of Amano).

Regarding claim 13, the device has a single skin depressing means positioned, in use, on one side of the artery (see entire document, especially fig. 14 of Amano).

Regarding claims 14 and 16, the device has a pair of skin depressing means 34 positioned on either side of the artery 94 (see entire document, especially fig. 2 of Amano).

With further regard to claim 16, the skin depressing means distal surfaces are each oriented substantially normally to the longitudinal direction of the artery (see entire document, especially fig. 2 of Amano).

Regarding claims 17, 18, 22, 25, 26, and 28, Amano discloses a method of transcutaneous waveform sensing of an artery, wherein at least some of the skin around the artery is flattened, depressed, and displaced in an application direction towards the artery, to a first depth, wherein the depth is dictated by the amount of pressure applied (see entire document, especially col. 11, lines 14-29 of Amano). The skin over the artery is also flattened, depressed, and display in the application direction to a second depth different from the first depth, wherein, again the depth is dictated by the amount of pressure applied (see entire document, especially col. 11, lines 10-13 of Amano). Since the pressure applied to the artery pressing section 14 varies over a wide range, the depth to which the skin in that area is displaced must at some point be different from the depth to which the skin in the vicinity of sensor pressing section 42 is displaced.

Regarding claim 18, figure 14 of Amano shows the first depth, which is the depth of depression around the artery, being greater than the second depth, which is the

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depth of depression over the artery (see entire document, especially figs. 2, 14 of Amano).

Regarding claim 22, the distance between the first depth and the second depth is variable, wherein the pressure applied to the artery pressing section 14 varies over a wide range, such that the depth to which the skin in the vicinity of the artery pressing section is displaced varies as that applied pressure varies.

Regarding claim 25, the skin around the artery on one side of the artery may be flattened, depressed and displaced (see entire document, especially fig. 14; col. 17, lines 15-55 of Amano).

Regarding claim 26, guides 34 are shown as being on either side of the artery and the sensor, and the skin under the guides is shown in figure 2 as being flattened, depressed, and displaced by the guides (see entire document, especially fig. 2 of Amano).

With further regard to claim 28, the skin around the artery on both sides of the artery include a pair of regions of the skin around the artery on either side of the artery and oriented substantially normally to the longitudinal direction of the artery (see entire document, especially fig. 2 of Amano).

Claims 1, 2, 4, 6, 8, 11-13, 17, 19, 20, 22, and 24-26 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent No. 6,394,959 to Takaya. Takaya teaches a device for transcutaneous pressure waveform sensing of an artery, the device having, in use, an application direction towards the skin of the user in the

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direction of an underlying artery. The device includes a pressure sensing head 60 having a distal end and at least one skin depressing means 66 having a distal surface 70, 76. The pressure sensing head distal end and skin depressing means distal surface are sides such that the pressure sensing head distal end is spaced apart in the application direction from the skin depressing means distal surface (see entire document, especially fig. 8; col. 8, lines 11-50 of Takaya).

Regarding claim 2, the pressure sensing head distal end protrudes from the skin depressing means distal surface in the application direction (see entire document, especially fig. 8 of Takaya).

Regarding claim 4, the distance between the skin depressing means distal surface and the pressure sensing head distal end is fixed, at least for some portion of time (see entire document, especially col. 8, lines 26-50 of Takaya).

Regarding claim 6, the distance between the skin depressing means distal surface and the pressure sensing head distal end is variable (see entire document, especially col. 8, lines 43-47 of Takaya).

Regarding claim 8, the skin depressing means is/are formed form a compressible material, wherein the skin depressing means comprises rubber bellows that may be filled with air, wherein such bellows are compressible (see entire document, especially col. 8, lines 30-36 of Takaya).

Regarding claim 11, the device has a single skin depressing means (see entire document, especially fig. 8; col. 8, lines 27-50 of Takaya).

Regarding claim 12, the skin depressing means has a substantially annular distal surface 76 (see entire document, especially fig. 8, col. 8, lines 33-47 of Takaya).

Regarding claim 13, the device has a single skin depressing means positioned, in use, on one side of the artery (see entire document, especially fig. 8 of Takaya).

Regarding claims 17, 19, 20, 22, and 24-26, the skin around the artery is flattened, depressed, and displaced in the application direction to a first depth by the skin depressing means 66, 70, 76 (see entire document, especially fig. 8; col. 8, lines 36-50 of Takaya). The skin over the artery is flattened, depressed, and displaced in the application direction to a second depth by the pressure sensing head 60 (see entire document, especially fig. 8; col. 8, lines 10-50 of Takaya).

Regarding claim 19, the second depth is greater than the first depth (see entire document, especially fig. 8; col. 13, lines 36-46 of Takaya).

Regarding claim 20, the distance between the first and second depths is fixed, at least for a short period of time (see entire document, especially col. 8, lines 10-50; col. 13, lines 27-64 of Takaya).

Regarding claim 22, the distance between the first and second depths is variable (see entire document, especially col. 8, lines 43-47; col. 13, lines 27-64 of Takaya).

Regarding claim 24, the region that is flattened, depressed and displaced around the artery is an annular region (see entire document, especially fig. 8; col. 8, lines 32-50 of Takaya).

Regarding claim 25, the skin on one side of the artery is flattened, depressed, and displaced (see entire document, especially fig. 8 of Takaya).

Regarding claim 26, the skin on both sides of the artery is flattened, depressed, and displaced (see entire document, especially fig. 8 of Takaya).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 15 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Amano, as applied to claims 1, 4, 6, 11, 13, 14, 16-18, 22, 25, 26, and 28 above. Amano is silent as to the shape of the depressing means distal surfaces. At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to use a hemispherical shape of the distal surfaces because the applicants have not disclosed that such a shape provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, moreover, would have expected the applicants' invention to perform equally well with any shape distal surfaces because the shape of the surface does not affect the ability of the device to detect the pressure waveform. Therefore, the use of a hemispherical shape of the distal surface or the displaced pair of regions being hemispherical is considered to be a mere design consideration that fails to patentably distinguish over the prior art of Amano.

Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Amano, as applied to claims 1, 4, 6, 11, 13, 14, 16-18, 17, 22, 25, 26, and 28 above. Amano is silent as to the distance between the first and second depths. At the time of invention, it would have been an obvious matter of design choice to a person of ordinary skill in the art to use a distance of 1.5 mm to 2.0 mm as the distance between the first and second depths since the applicants have not disclosed that such a depth provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, moreover, would have expected the applicants' invention to perform equally well with any reasonable distance, because the distance does not affect the ability of the device to detect the pressure waveform. Therefore, the use of a distance of approximately 1.5 to 2.0 mm is considered to be a mere design consideration that fails to patentably distinguish over the prior art of Amano.

Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Amano, as applied to claims 1, 4, 6, 11, 13, 14, 16-18, 17, 22, 25, 26, and 28 above. Amano is silent as to the shape of the pressure sensing head distal end. At the time of invention, it would have been an obvious matter of design choice to a person of ordinary skill in the art to use a circular shape as the shape of the pressure sensing head distal end since the applicants have not disclosed that such a shape provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, moreover, would have expected the applicants' invention to perform equally well with any shape distal end because the shape of the distal end does not affect the ability

of the device to detect the pressure waveform. Therefore, the use of a circular distal end or circular region of skin over the artery is considered to be a mere design consideration that fails to patentably distinguish over the prior art of Amano.

### ***Allowable Subject Matter***

Claims 7, 9, and 10 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The following is a statement of reasons for the indication of allowable subject matter:

Regarding claim 7, 9, and 10, the primary reason for allowance is the inclusion of a handle, wherein the distance between the skin depressing means distal surface(s) and the handle varies relative to the application pressure applied to the user's skin and the distance between the pressure sensing head distal end and the handle is fixed, in combination with all of the other limitations of the claims, which is not found in the prior art.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia C. Mallari whose telephone number is (571)

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272-4729. The examiner can normally be reached on Monday-Friday 10:00 am-6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II can be reached on (571) 272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Art Unit 3735